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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,423	11/26/2003	Gerard M. Jensen	01992.005US1	6232
	7590 05/14/200 RRIS & PADYS PLLI		EXAMINER	
P.O. BOX 1110			KISHORE, GOLLAMUDI S	
ST. PAUL, MN	1 33111-1098		ART UNIT PAPER NUMBER	
			1612	
			MAIL DATE	DELIVERY MODE
			05/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)					
Office Action Community	10/723,423	JENSEN ET AL.					
Office Action Summary	Examiner	Art Unit					
	Gollamudi S. Kishore, Ph.D	1612					
The MAILING DATE of this communicatio Period for Reply	n appears on the cover sheet with	the correspondence add	dress				
A SHORTENED STATUTORY PERIOD FOR R WHICHEVER IS LONGER, FROM THE MAILIN  - Extensions of time may be available under the provisions of 37 C after SIX (6) MONTHS from the mailing date of this communicatic  - If NO period for reply is specified above, the maximum statutory provided to reply within the set or extended period for reply will, by Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	NG DATE OF THIS COMMUNICATED FR 1.136(a). In no event, however, may a repon.  Deriod will apply and will expire SIX (6) MONTH statute, cause the application to become ABAI	ATION.  Note that the state of					
Status							
1) Responsive to communication(s) filed on							
	 This action is non-final.						
3) Since this application is in condition for al		re procedution as to the	morite is				
closed in accordance with the practice un	·	•	ments is				
closed in accordance with the practice un	dei Ex parte Quayle, 1955 C.D.	11, 455 O.G. 215.					
Disposition of Claims							
4)⊠ Claim(s) <u>24-30 and 39-52</u> is/are pending	in the application.						
4a) Of the above claim(s) is/are wit							
5) Claim(s) is/are allowed.	· · · · · · · · · · · · · · · · · · ·						
6) Claim(s) is/are rejected.							
7) Claim(s) is/are objected to.							
8)⊠ Claim(s) <u>24-30 and 39-52</u> are subject to r	estriction and/or election require	ment.					
Application Papers							
9)☐ The specification is objected to by the Exa	miner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Trib The datif of declaration is objected to by the	le Lammer. Note the attached	Since Action of formation	0-132.				
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for fo a) All b) Some * c) None of:  1. Certified copies of the priority docu 2. Certified copies of the priority docu 3. Copies of the certified copies of the application from the International B * See the attached detailed Office action for	ments have been received. ments have been received in Ap priority documents have been re ureau (PCT Rule 17.2(a)).	plication No eceived in this National S	Stage				
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-94  3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	8) Paper No(s)/	mmary (PTO-413) Mail Date ormal Patent Application -					



Application No.

## **DETAILED ACTION**

## Election/Restrictions

- This application contains claims directed to the following patentably distinct species
- 1) A liposomal formulation comprising HSPC:Choleserol: DSPG in a ratio of 4:1:0.1 and methods in claims 24, 29-30, 39, 44, 49, 54.
- 2) A liposomal formulation comprising DEPC: cholesterol in a ratio of 2:1 and methods in claims 25, 29-30, 40, 45, 50 and 55
- 3) A liposomal formulation comprising DEPC:cholesterol: DSPG in a ratio of 2:1::01 and methods in claims 26, 29-30, 41, 46, 51 and 56
- 4) A liposomal formulation comprising DOPC:cholesterol in ratio od 2:1 and methods in claims 27, 29-30, 42, 47, 52 and 57
- 5) A liposomal formulation comprising DMPC:cholesterol:DSPG in a ratio of 2:1:0.1 and methods in claims 28-30, 43, 48, 53 and 58

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none of the claims is generic.

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There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/ Primary Examiner, Art Unit 1612

**GSK**